Individual Safety Report

3230175-1-00-01

MEDWATCH THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

McNEIL

McNEIL CONSUMER PRODUCTS COMPANY
FORT WASHINGTON, PA 19034

Page ____ of ____

Approved by FDA on 11/15/93

Mfr report #

UF/Dist report #

FDA use only

A. Patient information

1. Patient identifier: unknown — In confidence
2. Age at time of event: or 41 yrs * — Date of birth:
3. Sex: ( )female (X)male
4. Weight: unk lbs or kgs

B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

( ) death (mo/day/yr)
( ) life-threatening
(x) hospitalization - initial or prolonged
( ) disability
( ) congenital anomaly
( ) required intervention to prevent permanent impairment/damage
( ) other:

3. Date of event (mo/day/yr): unknown

4. Date of this report (mo/day/yr): 03/19/99

5. Describe event or problem

Literature report (J Am Board Fam Pract 1998;(11)5:410-413) of ACUTE RENAL FAILURE in a 41 YO M w/a hx of alcoholism allegedly associated w/the use of an unknown acetaminophen product.According to case report,pt was admitted to hosp for HEMATEMESIS.Pt had been well until 12 days PTA when he drank 4-5 glasses of wine on that day.Pt began having flu-like sx & took approx 5g of acetaminophen(ie,about 3 extra-strength r 500mg acetaminophen tablets each day for 3 days).Nine ays PTA,pt went to local clinic c/o intractable NAUSEA & VOMITING.Pt dx w/viral HEPATITIS because of elevated LFTs. Pt offered symptomatic tx as op.N/V cont for 8 days w/one episode of hematemesis on day of admission.During this period,pt noticed a reduction in his urine output(OLIGURIA). On hosp day 1, FENa consistent w/oliguric acute TUBULAR NECROSIS.Pt underwent endoscopy & Mallory-Weiss tear was found.Pt's renal & liver functions gradually improved over next 5 days w/out dialysis.Pt was d/c on hosp day 8 w/creatinine level of 2.4 to a rehab facility for (See Sec C10)

6. Relevant tests/laboratory data, including dates

9 days PTA: Creat=1.9, AST=1590, ALT=4690; When examined: P=97, BP=117/76, T=nl, stool guaiac (+), WBC=14100, Hgb=10.4, Hct=30.5%, PT & PTT (WNL), serum albumin=4.4; Hosp Day 1: FENa=20.9%, BUN=135, Creat=14.3, ALT=63 (See Sec B7)

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

history of regular consumption of 1 gallon of whiskey per week for the past 10 years; denied IV drug abuse
Sec B6 cont: AST=316; Hosp Day 6: BUN 43, Creat=3.2, AST=119, ALT=146; Hosp Day 8 (day of discharge): BUN=23, Creat=2.4, AST=81, ALT= 133; hepatitis serologies (-) for epatitis A, B, C

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 unknown acetaminophen product
#2

2. Dose, frequency & route used
#1 1500 mg daily x 3 days
#2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 3 days
#2

4. Diagnosis for use (indication)
#1 flu-like symptoms
#2

5. Event abated after use stopped or dose reduced
#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No ( ) N/A

6. Lot # (if known)
#1 Unknown
#2

7. Exp. date (if known)
#1 Unknown
#2

8. Event reappeared after reintroduction
#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No ( ) N/A

9. NDC # - for product problems only (if known)
- -

10. Concomitant medical products and therapy dates (exclude treatment of event)
denied use of other prescription medications and OTC drugs (such as aspirin)
Sec B5 cont: therapy for alcoholism. At a 1 mo f/u, pt was asymptomatic & creatinine=0.9.

G. All manufacturers

1. Contact office - name/address (& mfr no. if devices)
McNeil Consumer Products Company
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

DSS
MAR 31 1999
ADVERSE EVENT REPORTING SYSTEM

2. Phone number: 215-273-7820

3. Report source (check all that apply)
( ) foreign
( ) study
(x) literature
( ) consumer
(x) health professional
( ) user facility
( ) company representative
( ) distributor
( ) other:

4. Date received by manufacturer (mo/day/yr): 03/18/99

5. (A) NDA # 19-872
IND #
PLA #
pre-1938 ( ) Yes
OTC product (X) Yes

6. If IND, protocol #

7. Type of report (check all that apply)
( ) 5-day (X) 15-day
( ) 10-day ( ) periodic
(X) Initial ( ) follow-up #

8. Adverse event term(s)
KIDNEY FAIL ACU
HEMATEMESIS
NAUSEA VOMIT
HEPATITIS
OLIGURIA
NECRO KIDNEY TU

9. Mfr. report number: 1144461A

E. Initial reporter

1. Name, address & phone #
[redacted] MD, PhD
University of [redacted] Medical Center
[redacted] St.
[redacted]

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EVALUATION AND RESEARCH

2. Health professional? (X) Yes ( ) No

3. Occupation: physician

4. Initial reporter also sent report to FDA: ( ) Yes ( ) No (X) Unk

FDA Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.